

REMARKS/ARGUMENTS

In response to the Office Action of January 12, 2004, Applicants request re-examination and reconsideration of this application for patent pursuant to 35 U.S.C. 132.

Claim Status/Support for Amendments

Claims 1, 39, 40 and 44-46 have been amended. Claims 2-38 were cancelled in a previous response (filed on July 15, 2003). Claims 39-46 are withdrawn from consideration. It is understood that claims 39-46, drawn to the non-elected invention, will remain pending, albeit withdrawn from prosecution on the merits at this time. If the examined claim of the Group I invention is deemed to be allowable, rejoinder of the remaining claims (39-46) in accordance with the decision in *In re Ochiai* is respectfully requested; since the remaining claims (39-46) are limited to the use of the biopolymer marker peptide of claim 1 (the examined claim of the elected Group I invention).

Claim 1 is currently under examination. Claims 1 and 39-46 remain pending in the instant application.

No new matter has been added by the amendments to the specification made herein.

The title of the invention has been amended to clearly

indicate the subject matter to which the pending claims are drawn; an isolated betaine/GABA transport protein biopolymer marker peptide.

In the "Background of the Invention" section a punctuation error was corrected at page 1, line 23.

The description of the reference at page 5 has been amended to correct a typographical error in the international application number. The corresponding international publication number has also been added.

The "Description of the Figures" section has been amended to add sequence identification numbers and to clearly indicate that Figures 2 and 3 show the mass spectrum profiles of the disclosed biopolymer markers.

Several protocols at pages 41-45 have been amended to properly identify trademark names (TRITON, TRIS and EPPENDORF). The protocol titles at page 41 (lines 6 and 20), page 42 (line 12) and page 43 (lines 3 and 16) were underlined in the original disclosure and do not indicate text amended herein.

The paragraph at page 46 has been amended to correct a typographical error.

In the "Detailed Description" section, the term "cerebrospinal fluid" has been added to define the abbreviation "CSF" at page 49, line 8 in order to provide additional support for cerebrospinal

fluid as recited in claim 41. "CSF" is a well known abbreviation for cerebrospinal fluid in the biochemical art. Kits for determining the presence of the claimed biopolymer markers are discussed at page 47, lines 6-23; cerebrospinal fluid is noted to be one type of sample which can be used in the discussed kits. A typographical error within the same paragraph has also been amended (skill replaced skilled).

The abstract has been amended to remove the legal phraseology ("said").

No new matter has been added by the amendments to the claims made herein.

Claim 1 has been amended to recite one biopolymer marker peptide, SEQ ID NO:2, see the instant specification at page 46, lines 4-10 and Figure 2. Claim 1 has also been amended to indicate the claimed biopolymer marker peptide is "isolated", i.e. separated from the coexisting materials of its natural state (see the instant specification at page 20, lines 9-16).

Claims 39 and 44 have also been amended to recite one biopolymer marker peptide, SEQ ID NO:2, see the instant specification at page 46, lines 4-10 and Figure 2. Claims 39 and 44 have also been amended to provide proper antecedent basis for the term "isolated biopolymer marker peptide".

Claim 40 has been amended to provide proper antecedent basis

for the term "sample".

Claims 45 and 46 have been amended to provide proper antecedent basis for the term "insulin resistance diagnostic kit".

Restriction

The Examiner indicates that newly submitted claims 39-46 are directed to inventions that are independent or distinct from the invention originally claimed, and since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 39-46 are withdrawn from consideration as being directed to a non-elected invention.

Request for Rejoining of Claims

Considering that claims 39-46 are limited to the use of SEQ ID NO:2 a search of these claims would encompass this specific peptide. The instant application is related in claim format to several other applications, both pending and issued, of which serial number 09/846,352 is exemplary. In an effort to maintain equivalent scope in all of these applications, Applicants respectfully request that the Examiner consider rejoining claims 39-46 in the instant application, which are currently drawn to non-

elected Groups, with claim 1 of the elected Group under the decision in *In re Ochiai* (MPEP 2116.01), upon the Examiner's determination that claim 1 of the elected invention is allowable and in light of the overlapping search. If the biopolymer marker peptide of SEQ ID NO:2 is found to be novel, methods and kits limited to its use should also be found novel.

Oath/Declaration

A new declaration, which has been properly executed and dated, is filed herewith because while the original oath filed on February 13, 2002 contains the signature of Dr. John Marshall (inventor 2), the date of signature was omitted.

Rejection under 35 USC 102(b)

Claim 1, as presented on July 15, 2003, stands rejected under 35 USC 102(b) as allegedly being anticipated by Borden et al. (US Patent 5,712,148).

The Examiner alleges that Borden et al. teach an isolated nucleic acid encoding GABA transporter where the sequence of positions 583-595 corresponds to the SEQ ID NO:2 recited in claim 1.

Applicants respectfully disagree with the Examiner's determination that the claimed subject matter is anticipated by

Borden et al.

It is well established that in order for a claim to be anticipated each and every element as set forth in the claim must be found, either expressly or inherently described in a single prior art reference (see MPEP 2131).

Borden et al. disclose the amino acid sequence of the human betaine/GABA transporter; see Figures 1a-1d and SEQ ID NO:2 of Borden et al. SEQ ID NO:2 as disclosed in the instant application represents a fragment of the betaine/GABA transporter 13 amino acid residues in length. SEQ ID NO:2 of the instant invention is identical to a portion of SEQ ID NO:2 of Borden et al.

Claim 1 has been amended herein to recite an isolated biopolymer marker peptide consisting of SEQ ID NO:2. Since "consisting of" is closed language and excludes any element, step or ingredient not specified in the claim (see MPEP 2111.03), the scope of the instant claim 1 now encompasses only this specific peptide (SEQ ID NO:2), thus excluding the larger protein sequence disclosed by Borden et al. (SEQ ID NO:2 of Borden et al.).

Accordingly, since the sequence of the instant invention is distinct from the sequence of Borden et al. , the reference (Borden et al.) can not be said to describe each and every element set forth in claim 1 as amended herein. Thus, the Examiner has failed to present a reference which properly anticipates the claim.

Applicants respectfully submit that they have now demonstrated how the sequence as instantly claimed distinguishes over the sequence taught by Borden et al. and respectfully request that this rejection under 35 USC 102(b) be withdrawn.

Rejection under 35 USC 102(e)

Claim 1, as presented on July 15, 2003, stands rejected under 35 USC 102(e) as allegedly being anticipated by Durham et al. (US Published Application 2002/0164668).

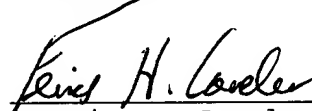
The Examiner asserts that Durham et al. teach using various peptide biomarkers for detecting Alzheimer's disease encompassing the instant recited SEQ ID NO:1. Therefore, the Examiner alleges that Durham's reference anticipates the instant invention and notes that the current claim is considered a product claim, thus no patentable weight is given to the intended use.

Claim 1 has been amended herein and does not recite SEQ ID NO:1. Thus, the rejection of claim 1 under 35 USC 102(e) as allegedly being anticipated by Durham et al. (US Published Application 2002/0164668) is rendered moot. Accordingly, Applicants respectfully request that this rejection under 35 USC 102(e) be withdrawn.

CONCLUSION

In light of the foregoing remarks, amendments to the specification and amendments to the claims, it is respectfully submitted that the Examiner will now find the claims of the application allowable. Favorable reconsideration of the application is courteously requested.

Respectfully submitted,



Ferris H. Lander
Registration # 43,377

McHale & Slavin, P.A.
2855 PGA Boulevard
Palm Beach Gardens, FL 33410
(561) 625-6575 (Voice)
(561) 625-6572 (Fax)

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